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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/864,891	05/24/2001	Kok-Hwee Ng	F-5735 (1417P P 599)	2261

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EXAMINER

TOMASZEWSKI, MICHAEL

ART UNIT	PAPER NUMBER
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3626

DATE MAILED: 06/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/864,891

Applicant(s)

NG ET AL.

Examiner

Mike Tomaszewski

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>08/29/2001</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice To Applicant

1. This communication is in response to the application filed 24 May 2001 and the preliminary amendments filed 02 August 2002 and 27 August 2001. Claims 1-7 were canceled in the preliminary amendment filed 02 August 2002. Claims 8-53 are pending.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 43-53 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The basis of this rejection is set forth in a two-prong test of:

- (1) whether the invention is within the technological arts; and
- (2) whether the invention produces a useful, concrete, and tangible result.

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(A) For a claimed invention to be statutory, the claimed invention must be within the technological arts. Mere ideas in the abstract (i.e., abstract idea, law of nature, natural phenomena) that do not apply, involve, use, or advance the technological arts fail to promote the "progress of science and the useful arts" (i.e., the physical sciences as opposed to social sciences, for example) and therefore are found to be non-statutory subject matter. For a process claim to pass muster, the recited process must somehow apply, involve, use, or advance the technological arts.

In the present case, exemplary claim 43 is drawn to a method for managing inventory of blood collection soft goods and for preventing the use of quarantined soft goods, the method comprising the step of performing...; accessing...; and indicating. It is not clear whether or not the recited steps of performing, accessing, and indicating actively apply, involve, use, or advance the technological arts. In particular, these acts are capable of being performed in the human mind or via paper and pencil. Further, it is respectfully submitted that a "system database" in its broadest reasonable interpretation, may be construed to be a centralized file cabinet or a master collection of index cards. As such, there is no specific requirement with the language of the claim to a practical application WITHIN the technological arts, as there is no requirement for any of the recited steps to be performed electronically or via computerized database components.

Additionally, for a claimed invention to be statutory, the claimed invention must produce a useful, concrete, and tangible result. In the present case, exemplary claim 43 is drawn to a method for managing inventory of blood collection soft goods and for

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preventing the use of quarantined soft goods, and as such, appears to produce a useful, concrete, and tangible result, namely an inventory of specialized items.

Although the recited process produces a useful, concrete, and tangible result, since the claimed invention, as a whole, is not within the technological arts as explained above, claim 43 is deemed to be directed to non-statutory subject matter.

(B) Dependent claims 44-53 fails to further recite a positive and definite limitation to the technological arts, and also fail to pass muster under 35 U.S.C 101

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claim 8-53 are rejected under 35 U.S.C. 102(e) as being anticipated by Fletcher-Haynes et al. (US 2001/0034614 A1; hereinafter Fletcher-Haynes).

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(A) As per claim 8, Fletcher-Haynes discloses a system for managing inventory of blood component collection soft goods and for preventing the use of quarantined soft goods, the system comprising:

- (i) a blood component collection instrument for collecting a blood component from a blood component donor (Fletcher-Haynes; par. [0056]);
- (ii) a system computer being operably connected to the blood component collection instrument (Fletcher-Haynes; par. [0057]), the system computer running a blood component collection application for at least a portion of a blood component collection process (Fletcher-Haynes; par. [0057]), wherein the system computer is in data communication with a system database having a blood component collection soft good inventory (Fletcher-Haynes; par. [0011] and [0195]); and
- (iii) an interface being operably connected to the system computer, the interface having a quarantine field for indicating that at least a portion of the blood component collection soft good inventory is quarantined (Fletcher-Haynes; par. [0162]; the Examiner considers the time components of Fletcher-Haynes to be a form of quarantine time, put another way, the Examiner considers the soft good to be quarantined during the time between the initial collection time to the collection end time).

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(B) As per claim 9, Fletcher-Haynes discloses the system of claim 8, wherein the interface communicates to the system database an identification of the quarantined soft goods (Fletcher-Haynes; par. [0083], par. [0125] and [0162]).

More specifically, the Fletcher-Haynes interface has the capability of identifying quarantined soft goods in numerous ways including, but not limited to, a donation unit number, barcode, and/or product type (e.g., platelets, plasma, red blood cells, inter alia) (Fletcher-Haynes; par. [0083], [0125] and [0162]).

(C) As per claim 10, Fletcher-Haynes discloses the system of claim 8, wherein the blood component collection soft good is selected from a group consisting of a blood component collection kit, a blood component collection solution, and a blood component collection transfer pack (Fletcher-Haynes; par. [0315]).

Fletcher-Haynes teaches that the blood, and in turn, the blood component soft good, may be selected from a myriad of sources including any appropriate containers (i.e., kits, packs, bags, etc.), donors, whether human or animal, collection solutions and the like (Fletcher-Haynes; par. [0315]).

(D) As per claim 11, Fletcher-Haynes discloses the system of claim 8, wherein the interface further comprises a reader being operably connected to the system computer for receiving an operator identifier and transmitting the operator identifier to the system computer, and for receiving separate input of a blood component and soft good

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identifier and transmitting the blood component soft good identifier to the system database (Fletcher-Haynes; par. [0059] and [0071]).

In short, Fletcher-Haynes teaches the use of a multitude of identifiers (e.g., operator identifiers, instrument/device/machine identifiers, donor identifiers, soft good identifiers, etc.) being received and transmitted by the system computer in conjunction with an array of peripheral hardware components (e.g., barcode readers, scanners, cameras, etc.) (Fletcher-Haynes; par. [0059] and [0071]).

(E) As per claim 12, Fletcher-Haynes discloses the system of claim 11, wherein the operator identifier and a blood component collection soft good identifier are received from a location proximate the blood component collection instrument (Fletcher-Haynes; par. [0058] and [0059]).

(F) As per claim 13, Fletcher-Haynes discloses the system of claim 8, wherein the system database is integral with the system computer (Fletcher-Haynes; par. [0057] and [0058]).

In fact, Fletcher-Haynes teaches multiple system configurations including, but not limited to, one where the system database can be included therein (i.e., integral within the computer), one where the system database is positioned in close proximity with the system computer (i.e., integral to the computer system), and one where there system database is located remotely (i.e., integral to the computer system network) (Fletcher-Haynes; par. [0057] and [0058]).

(G) As per claim 14, Fletcher-Haynes teaches the system of claim 8, further comprising a blood component collection donor identifier corresponding to a blood component donor, wherein the blood component collection donor identifier is transmittable to the system computer for storing the blood component collection donor identifier in the memory and for associating the blood component collection donor identifier with at least one of the blood component collection soft good identifier and the blood collection instrument identifier (Fletcher-Haynes; par. [0142] and [0167]).

(G) As per claim 15, Fletcher-Haynes discloses the system of claim 8, wherein the blood component collection instrument further comprises a blood component collection instrument identifier (i.e., machine ID) (Fletcher-Haynes; par. [0159]).

(H) As per claim 16, Fletcher-Haynes discloses the system of claim 8, wherein the interface utilizes radio frequency to transmit to the system computer (Fletcher-Haynes; par. [0059]).

In fact, Fletcher-Haynes teaches an open computer system architecture that may leverage a broad assortment of interface transmission means including cable, satellite, and energy wave communication (Fletcher-Haynes; par. [0059]).

(I) As per claim 17, Fletcher-Haynes discloses the system of claim 8, further comprising:

- (i) a system communication conduit for operably connecting the system computer to the blood component collection instrument (Fletcher-Haynes; par. [0012]); and
 - (ii) a system communication protocol for facilitating communication on the communication conduit between the system computer and the blood component collection instrument (Fletcher-Haynes; par. 0030)).
- (J) As per claim 18, Fletcher-Haynes discloses the system of claim 17, wherein the system communication protocol is Ethernet (Fletcher-Haynes; par. [0030]).
- (K) As per claim 19, Fletcher-Haynes discloses the system of claim 17, wherein the system communication protocol is TCP/IP (Fletcher-Haynes; par. [0030]).
- (L) As per claim 20, Fletcher-Haynes discloses the system of claim 17, further comprising:
- (i) a network server being operably connected to the system computer via a network communication conduit (Fletcher-Haynes; par. [0012] and [0065]); and

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- (ii) a web interface being operably connected to the system computer for facilitating access to the blood component collection process, wherein the interface receives data from the system computer (Fletcher-Haynes; par. 0033]).

(M) As per claim 21, Fletcher-Haynes discloses the system of claim 20, further comprising a web server being operably connected to the system computer and operably responsive to a web browser wherein the information stored in the system computer can be accessed (Fletcher-Haynes; par. [0194]).

(N) As per claim 22, Fletcher-Haynes discloses the system of claim 20, wherein the interface comprises a reader having at least one of a touch pad, a keypad, an optical scanner, and a magnetic scanner (Fletcher-Haynes; par. [0057], [0065] and [0152]).

(O) As per claim 23, Fletcher-Haynes discloses the system of claim 8, wherein the system database further comprises separate inventory data for each of a plurality of different types of soft goods (Fletcher-Haynes; par. [0166]).

More specifically, Fletcher-Haynes teaches the capability of capturing, editing, printing, manipulating, measuring, modifying, calculating, transmitting and receiving voluminous amounts of diverse data pertinent to the apheresis process such as blood component soft good data, donor data, instrument data, collection process data, inventory data, dates, times, etc (Fletcher-Haynes; par. 0166] and [0167]).

(P) As per claim 24, Fletcher-Haynes discloses the system of claim 23, wherein the plurality of different types of soft goods is selected from a group consisting of a blood component collection kit, a blood component collection solution, and a blood component collection transfer pack (Fletcher-Haynes; par. [0315]).

(Q) As per claim 25, Fletcher-Hayes discloses the system of claim 8, wherein the blood component soft good inventory data is modified in response to the receipt of the blood component soft good identifier transmitted from the interface (Fletcher-Hayes; par. [0166]).

(R) As per claim 26, Fletcher-Haynes discloses the system of claim 25, wherein the system computer generates a notification (e.g., prompts) when the blood component soft good inventory data is modified to a value, which is lower than a predetermined value (Fletcher-Haynes; par. [0314]).

(S) As per claim 27, Fletcher-Haynes discloses the system of claim 26, wherein the notification comprises providing a reorder option corresponding to the blood component soft good associated with the blood component soft good identifier (Fletcher-Haynes; par. [0195]).

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(T) As per claim 28, Fletcher-Haynes discloses the system of claim 27, wherein the notification is transmitted to a remote access service for restocking blood component soft good inventory (Fletcher-Haynes; par. [0195] and [0314]).

(U) As per claim 29, Fletcher-Haynes discloses the system of claim 8, further comprising a blood component collection kit having a plurality of blood component collection soft goods (Fletcher-Haynes; par. [0315]).

(V) As per claim 30, Fletcher-Haynes discloses the system of claim 29, wherein the blood component collection kit comprises a blood component container, a hypodermic needle, a blood component sample container, and a label (e.g., barcode) (Fletcher-Haynes; par. [0071 and par. [0192]).

(W) Claim 31 differs from system claim 8 by reciting “[a] computer readable medium having computer program code stored thereon...” within its preamble. As per these elements, Fletcher-Haynes’ system and method for managing inventory of blood component collection soft goods includes computers, data storage devices, communication devices, server systems, network systems and software applications running in tandem with various hardware devices (Fletcher-Haynes; par. [0020], [0031], [0032] and [0057]). As such, it is readily apparent that Fletcher-Haynes’ system and method for managing inventory of blood collection soft goods is controlled by a computer program stored upon a computer-readable medium.

The remainder of claim 31 repeats the same limitations of claims 8, and is therefore rejected for the same reasons given for claim 8 above, and incorporated herein.

(X) Claims 32-42 repeat the same limitations of claims 9-12, 14-15 and 25-28, and are therefore rejected for the same reasons given for those claims.

(Y) Method claim 43 differs from system claim 8 by excluding hardware and software elements, namely, "a blood component collection instrument," "a system computer being operably connected to the blood collection instrument," "the system computer running a blood component collection application," "a system database having a blood component collection soft good inventory," and "an interface being operably connected to the system computer, the interface having a quarantine field." The method appears to merely recite the underlying process steps of system claim 8 and thus merely repeats the same limitations of claims 8, and is therefore rejected for the same reasons given for claim 8 above, and incorporated herein.

(Z) Claims 44-53 repeat the same limitations of claims 9-12, 14-15 and 25-27, and are therefore rejected for the same reasons given for those claims.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied art teaches a blood component collecting apparatus (6,752,777); an automatic whole blood collection system (6,113,554); a blood collecting and processing means (3,926,521); a blood separation device (5,318,512); a method and apparatus for treating blood (6,083,187); the use of blood and plasma donor samples and data in the drug discovery process (US 2002/0046054 A1); a diagnostic assay system using a kit for collecting and storing a test sample, the kit including a sample collection device, a sample storage device, and a printed material having indicated thereon an electronic address for accessing the result of the assay (US 2002/0055176 A1); and an apheresis apparatus and method for producing blood products (6,743,192).

The cited but not applied art also includes non-patent literature articles by Tim Bonfield ("New Collection Method Draws More Blood Units" Aug. 23, 2000. Cincinnati Enquirer. FINL Edition. pg. B.01.); Total Apheresis ("Multicomponent Collection (MCC) With the Latest Hemapheresis Apparatuses" Sep. 13, 1999. Pain & Central Nervous System Week. pg. 1)); TB & Outbreaks Weekly ("Blood Components; "A New Apheresis Procedure for the Preparation of High-Quality Red Cells and Plasma" Aug. 9, 1999. pg. 19.); TB & Outbreaks Weekly ("Transfusion Medicine; "Collection of Two Peripheral Blood Stem Cell Concentrates From Healthy Donors" May 10, 1999. pg. 18.); Business Editors and Health/Medical Writers ("Haemonetics' Double Red Blood

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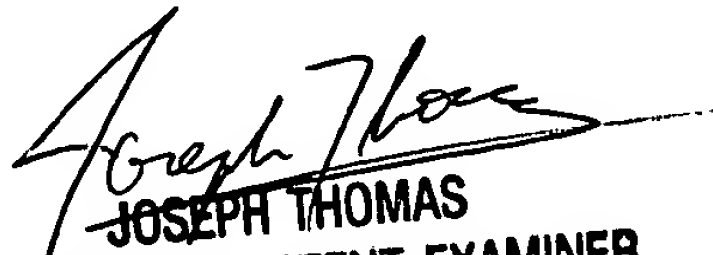
Cell Collection Technology Can Improve Blood Supply" Mar. 24, 1999. Business Wire. pg. 1.); Blood Weekly ("Leukocyte Filtration; "Improved Removal of White Cells with Minimal Platelet Loss by Filtration of Apheresis Platelets During Collection" Blood Weekly. Feb 22, 1999. pg. 15-16.); and Health/Medical Writers ("Speedy FDA Approval of Haemonetics' New Platelet Collection Bags to Benefit Blood Centers, Hospitals, and Patients" Business Wire. Jan 18, 1999. pg. 1.).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mike Tomaszewski whose telephone number is (571)272-8117. The examiner can normally be reached on M-F 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571)272-6776. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MT ~~WA~~ 5.15.05


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